ISRCTN14227980 https://doi.org/10.1186/ISRCTN14227980

Evaluation of the anti-arrhythmic effects of 3 dosages of S 44121 versus placebo in patients with chronic heart failure at risk for ventricular arrhythmia

Submission date 27/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/05/2010	**Overall study status** Completed	
Last Edited 20/04/2020	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-014940-12

Protocol serial number
CL2-44121-006

Study information

Scientific Title
Evaluation of the anti-arrhythmic effects of 3 oral dosages of S 44121 versus placebo in patients with chronic heart failure and left ventricular systolic dysfunction at risk for ventricular arrhythmia: a 12-week, randomised, double-blind, parallel-group, placebo controlled, international multicentre study

Study objectives
To evaluate the anti-arrhythmic efficacy of S 44121 versus placebo in patients with chronic heart failure and left ventricular systolic dysfunction for prevention of ventricular arrhythmia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Randomised double-blind parallel-group placebo-controlled international multicentre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiac arrhythmia in chronic heart failure

Interventions
A 2-week run-in period followed by 12-week randomised double-blind period of S 44121 versus placebo, and a 2-week follow-up period.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
S 44121

Primary outcome(s)
Efficacy measurements recorded on the Holter ECG, measured at at inclusion visit and 1 week, 4 weeks and 12 weeks of treatment

Key secondary outcome(s))
1. Safety profile measured by 12-lead resting ECG, measured at each visit
2. Physical examination, measured at each visit

3. Adverse events, recorded throughout the study
4. Blood clinical laboratory parameters, measured at at inclusion visit and after 12 weeks of treatment

Completion date
28/02/2013

Eligibility

Key inclusion criteria
1. Both genders patients between 18 years or legal age and 80 years
2. Symptomatic chronic heart failure for at least 6 months
3. Ischaemic disease or idiopathic dilated cardiomyopathy as main cause for chronic heart failure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
149

Key exclusion criteria
1. Women who are pregnant, breast-feeding or not using contraception
2. Recent myocardial infarction, unstable angina or coronary revascularisation less than 3 months before selection
3. History of stroke or cerebral transient ischemic attack within the previous 3 months before selection

Date of first enrolment
01/03/2010

Date of final enrolment
28/02/2013

Locations

Countries of recruitment
United Kingdom

England

Argentina

Australia

Belgium

Canada

Czech Republic

France

Germany

Hungary

Korea, South

Netherlands

Poland

Portugal

Singapore

Slovakia

Spain

Taiwan

Study participating centre
St. Georges' University of London
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Basic results			20/04/2020	No	No